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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,768	02/10/2004	Antonios G. Mikos	01997/518004	8716
21559	7590	06/29/2006		EXAMINER
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110				NAFF, DAVID M
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/775,768	MIKOS ET AL.	

### Office Action Summary

Examiner

David M. Naff

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→ The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 February 2004.
- 2a) This action is FINAL.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 11-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 11-13 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 10 February 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/23/05.

- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

A preliminary amendment of 2/10/04 canceled claims 1-10, and added new claims 11-13.

A preliminary amendment of 6/14/04 amended the specification.

5 Claims examined on the merits are 11-13, which are all claims in the application.

***Specification***

The disclosure is objected to because of the following informalities: this application cannot be a continuation of parent 10 application 09/669,760 as stated in the first paragraph of the specification since this application has a different inventive entity from the parent application. An inventorship change should be made in this application as in the parent application. Furthermore, this application cannot be continuation of parent application 08/052,387 15 unless the inventorship change in 09/669,760 was also made in 08/052,387.

Appropriate correction is required.

It is noted that the Vacanti et al (Journal of Pediatric Surgery) listed on form 1449 has a publication date of Jan 98. However, patent 20 5,514,378 gives the date as 1988. Which is correct?

***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical 25 subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In*

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*re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

5 A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

10 Claim 11 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,689,608 B1. This is a double patenting rejection.

Claim 11 is identical to that of claim 1 of the patent.

#### **Double Patenting**

15 The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, 20 e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 30 644 (CCPA 1969).

35 A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

40 Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-

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7 of U.S. Patent No. 6,689,608 B1 in view of Vacanti et al (5,759,830).

The polymeric matrix of the claims of the patent is the same as presently claimed except for matrix comprising cells as required by 5 claim 12 and comprising a material enhancing cell attachment as required by claim 13.

Vacanti et al disclose attaching cells to a polymeric matrix. Different types of cells can be attached (col 6, lines 27-34), and the matrix can be coated with a coating that enhances cell attachment (col 10 10, lines 43-48).

Since the matrix of the patent claims is required by the claims to be suitable for attachment and proliferation of cells, it would have been obvious to attach to the matrix of the patent claims cells disclosed by Vacanti et al for attaching to a matrix. It would have 15 been further obvious to coat the matrix of the patent claims with a cell attachment enhancing coating as disclosed by Vacanti et al to obtain the attachment enhancing function of the coating.

#### ***Double Patenting***

Claim 11 is rejected on the ground of nonstatutory obviousness-type 20 double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,514,378. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent require a method for producing a porous biocompatible synthetic polymer membrane wherein crystallinity is 25 modified (claim 2), the membrane has a porosity of greater than 90%

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(claim 9), and particles are used that will produce a pore size of 100-500 microns (claim 4). When modifying the crystallinity as claimed by claim 2 of the patent, it would have been obvious to select a preferred optimum degree of crystallinity of 0-24.5% as presently 5 claimed. A membrane from the method of the patent claims having this crystallinity will be a matrix that is the same as the presently claimed matrix.

***Double Patenting***

Claims 12 and 13 are rejected on the ground of nonstatutory 10 obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,514,378 in view of Vacanti et al (5,759,830).

It would have been obvious to attach cells to the membrane resulting from the process of the patent claims to obtain the function of cells attached to the membrane as suggested by Vacanti et al when 15 attaching cells to a matrix since the membrane resulting from the method of the patent claims is biocompatible. Vacanti et al would have further suggested coating the membrane with a cell attachment enhancing coating as required by claim 13 to enhance cell attachment.

The patents listed on form PTO-892 other than applied are patents 20 made of record in parent application 09/669,760.

***Conclusion***

Any inquiry concerning this communication or earlier 25 communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

5 Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For 10 more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651

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DMN  
6/23/09